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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,753	03/14/2001	Erwin W. Gelfand	2879-74	5001

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SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/809,753	GELFAND ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,12-14,20-26,29,30,43,44 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-10, 12-14, 20-26, 29-30, 43-44, and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/5/07 has been entered.

2. Claims 1, 3-10, 12-14, 20-26, 29-30, 43-44, and 46 are pending and are being acted upon in this Office Action.

3. The request for interference filed 6/5/07 is acknowledged. However, examination of this application has not been completed as required by 37 CFR 41.102(a). Consideration of a potential interference is premature. See MPEP § 2303.

4. Applicant failed to (1) identify all claims the applicant believes interfere, and/or (2) propose one or more counts, and/or (3) show how the claims correspond to one or more counts. See 37 CFR 41.202(a)(2) and MPEP § 2304.02(b).

5. Applicant failed to provide a claim chart comparing at least one claim of each party corresponding to the count. See 37 CFR 41.202(a)(3) and MPEP § 2304.02(c).

6. Applicant failed to provide a detailed explanation as to why applicant will prevail on priority. See 37 CFR 41.202(a)(4), (a)(6), (d) and MPEP § 2304.02(c).

7. Because of the reasons stated above, all rejections remain.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in—

(1)an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in

section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

9. Claims 1, 3-5, 8-9, 12, 20-26, 29-30, 43-44 and 46 stand rejected under 35 U.S.C. 102(e) as being anticipated by US Pat 6,743,429 B2 (filed 12/24, 1999; PTO 1449) as evidence by Beaupre et al (of record, Thorax 36(10): 731-6, Oct 1981; PTO 892).

The '429 patent teaches a method to inhibit allergen-induced airway hyperresponsiveness in a mammal such as guinea pigs, sheep (see col. 12, lines 53, col. 18, line 56-67, in particular) and human by administering to the mammal a calcitonin gene related peptide such as human CGRP, rat CGRP and human αCGRP (see claims 1-3 of the '492 patent, col. 8, line 36-39, col. 7, lines 36-39, in particular). The reference mammal has been sensitized to an allergen that induces airway hyperresponsiveness (see claim 1 and 3 of the '429 patent, in particular). The reference CGFP is administered 15 to 20 minutes prior to exposure to AHR provoking stimulus such as Ovalbumin (see col. 13, line 39-41, col. 16, lines 2-4, col. 19, lines 60-67, claim 3 of '492 patent, in particular). The reference method further comprises monitoring the mammal to detect whether airway hypersensitivity is inhibited (see col. 15, lines 14-25, in particular). The reference CGRP is targeted to cells in the lung such as smooth muscle cells (see col. 3, lines 20, in particular) and epithelial cells of the tracheobronchial tree (see col. 3, line 59-67, in particular). The reference CGRP is administered by direct delivery to the lung of the mammal by aerosol spray (see col. 11, lines 60-67, col. 19, lines 31-32, claim 13 of '429 patent, in particular) or parenteral or oral (see col. 12, lines 1-5, in particular). The reference CGRP is administered in a pharmaceutically acceptable excipient (see col. 11, lines 49-57, and col. 12, lines 25-31, in particular). The '429 patent further teaches a method of inhibiting allergen-induced airway hyperresponsiveness in a mammal such as sheep comprising administering to the sheep a calcitonin gene related peptide (CGRP) wherein the sheep has allergen-induced airway hyperresponsiveness in response to a concentration of metacholine (see col. 19, lines 31-46, Figure 9, in particular). The recitation of provoking agent that causes a 20% fall in FEV1(PC20FEV1) wherein said concentration is less than the concentration required to cause a 20% fall in FEV1(PC20FEV1) in allergen-sensitized animal is within the teachings of the '429 patent. The evidentiary reference Beaupre et al teach that PC20FEV1 is the concentration of provoking agent such as histamine that causes a 20% fall in FEV1 and PC20FEV1 is a merely an index in characterizing the clinical state of asthmatic (see

abstract, in particular). In fact, the instant specification discloses a variety of provoking agents such as histamine, acetylcholine and metacholine are useful in measuring AHR values (see page 14, last paragraph of instant specification) and FEV1 and FVC values can be measured using methods known to those of skill in the art (see page 14, line 4-8, in particular). The '429 patent teaches that pretreatment of CGRP at various concentrations such as 10^{-9} to 10^{-6} M, which is about 0.1 μg/ kg body weight to about 10 or 5 about μg/ kg body weight of the reference mammal (see col. 13, lines 18-20, in particular). The term "about" expands the claimed range to include the reference concentration. Claims 5 and 8-9 are included in this rejection because the reference teaches administering CGRP five minutes prior challenge and this step is repeated, and five minutes is within 12 hours, 2 hours or between 48 hours or less prior to exposure to AHR provoking stimulus. Thus, the reference teachings anticipate the claimed invention.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 6-7, 10 and 13-14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat 6,743,429 B2 (filed 12/24, 1999; PTO 1449) as evidence by Beaupre et al (of record, Thorax 36(10): 731-6, Oct 1981; PTO 892).

The teachings of the '429 patent as evidence by Beaupre et al have been discussed supra.

The claimed invention in claim 6 differs from the teachings of the reference only that the method wherein the agent is administered upon the detection of the first symptoms of AHR.

The claimed invention in claim 7 differs from the teachings of the references only that the method wherein the agent is administered within one hour after the detection of the first symptoms of AHR.

The claimed invention in claim 10 differs from the teachings of the reference only in that the method wherein the agent is administered every one to two days.

The claimed invention in claim 13 differs from the teachings of the reference only in that the method wherein the agent is administered at a dose of from about 0.1 μg x kilogram-1 and about 10 μg x kilogram body weight of said mammal.

The claimed invention in claim 14 differs from the teachings of the reference only in that the method wherein the agent is administered at a dose of from about 0.1 μg x kilogram-1 and about 5 μg x kilogram body weight of said mammal.

The '429 patent further teaches it will be appreciated that optimum dosages will be determined by standard methods for each treatment modality such as age, weight, and conditions such as taking into account of its severity, the duration of desired treatment, the route of administration and the like (see col. 12, lines 29-36, in particular). It is well within the purview of one of ordinary skill in the medicinal art to optimize dosing schedules for a particular treatment regimen and dosage as taught by the '429 patent.

13. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

15. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/
Patent Examiner
Technology Center 1600
August 17, 2007